REMARKS/ARGUMENTS

Claims 6-26 are pending. Claims 6, 12 and 25 have been revised to refer to polynucleotides instead of genes. Claims 7-11 have been revised for clarity. New Claim 26 is directed to a method using a polynucleotide encoding indoleacetamide hydrolase, such as the iaaH gene, and finds support in the original claims and in the specification on page 6, first paragraph. Accordingly, the Applicants do not believe that any new matter has been introduced.

Rejection - 35 U.S.C. §112, second paragraph

Claim 6-25 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. This rejection is moot in view of the amendment of Claim 6 above.

Rejection - 35 U.S.C. §112, first paragraph

Claims 6-11 and 13-24 were rejected under 35 U.S.C. §112, first paragraph, as lacking adequate written description. The Applicants respectfully traverse this rejection for the reasons below.

Initially, the Appellants note that the specification, explicitly discloses this term on page 4, lines 15-16: ". . .an auxin precursor-auxin synthesis gene is used as a selectable marker gene". Moreover, the specification describes the particular selectable marker genes, such as *iaaH* and *iaaM* (page 4, last three lines). Therefore, there is no issue of whether or not the specification literally describes this term.

Rather, the issue of description appears to refer to whether the term "selectable marker polynucleotide" adequately describes the structures of the selectable marker polynucleotides (or genes) used in the claimed method. The rejection refers to Amgen and Eli Lilly and is premised on lack of structural description for the "selectable marker

polynucleotide" recited by independent Claim 6. It also applies to the "cytokinin synthesis gene" which appears in dependent Claim 13.

The Applicants traverse this description rejection based on the recent decision in Capon v. Eshhar, 76 USPQ2d 1078 (CA FC 2005). This decision held that description of well-known element is not a *per se* requirement. Capon indicates that the written description requirement must be "applied in the context of the invention and the state of knowledge in the art", (page 15, lines 3-4) and that it was error to hold that "the specifications do not meet the written description requirement because they do not reiterate the structure or formula or chemical name for the [claimed] nucleotide sequences" (page 15, last paragraph).

The written description requirement serves to ensure that the inventor had possession, as of the filing date, of the subject matter later claimed. How the specification accomplishes this is not material, see In re Alton, 76 F.3d 1168, 1172 (Fed. Cir. 1996). Determining whether written description requirement is satisfied, requires the disclosure to be read in light of the knowledge possessed by those skilled in the art. Such knowledge can be established by an affidavit of fact from an expert, and by patents and publications available to the public prior to the filing date of the application--see In re Alton, *id.* and In re Lange, 644 F.2d 856 (C.C.P.A. 1981).

The description issue in the present application is on point with the situation in Capon since auxin precursor-auxin synthesis genes were well-known in the art as of the filing date of this application. As shown by Woodward et al., Annals of Botany 95:707 many such genes were known, see Table 1 on page 710.

Moreover, like the situation in Capon, the nature of the invention "does not concern the discovery of gene function or structure, as in Lilly" (Capon, page 15, last paragraph) and there is no requirement in the case law to provide re-analysis (or re-description) of known DNA sequences, see page 14 of Capon:

Similarly to Capon the selectable marker polynucleotides of the invention:

> None of the cases to which the Board attributes the requirement of total DNA re-analysis, i.e., Regents v. Lilly, Fiers v. Revel, Amgen, or Enzo Biochem, require a re-description of what was already known. In Lilly. . .the cDNA for human insulin had never been characterized. . .

Accordingly, the description issue pertaining to the present method claims is on point with Capon, but not with Lilly since the present invention does not concern the discovery of the structure or function of the DNAs encoding the three enzymes. Rather, the structures and functions of the polynucleotides (i.e., selectable markers and cytokinin synthesis genes) required by the claims were already well-known in the art and should not have to be re-analyzed and re-described by the Appellants to meet the description requirement. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

Rejection - 35 U.S.C. §112, first paragraph

Claims 6-24 were rejected under 35 U.S.C. §112, first paragraph, as lacking adequate enablement. The Applicants traverse this rejection for the reasons discussed below.

Initially, there is no requirement that a patent applicant actually exemplify the claimed subject matter for it to be enabled. Rather, the test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary it is undue, *In re Angstadt*, 190 USPQ 214, 219 (CCPA 1976); MPEP 2164.01(a).

No undue experimentation is required to practice the claimed methods because:

(A) the breadth of the present claims limits the selectable marker polynucleotides (genes) to those which encode "an enzyme that synthesizes auxin from an auxin precursor or synthesizes an auxin analogue from an auxin analogue precursor". There are a limited number of such genes and such genes are well-known to those of skill in the art, see e.g. Woodward et al., *id.*

(B) The nature of the invention involves a method for producing a transgenic plant, and not the identification of particular selectable marker polynucleotides. The claimed method steps are straightforward and well within the skill of those in the art.

(C) The state of the prior art shows that methods for producing transgenic plants are well-known and that genes involved in auxin or auxin-precursor synthesis are well-known.

(D) The level of ordinary skill in the molecular biological arts is high, generally Ph.D or post-doctoral level.

(E) The level of predictability in the art is high, since methods for obtaining, culturing and selecting plant cells and producing plant tissues and transgenic plants are well-known. Selection of transgenic tissues using selectable markers and cultivating transgenic plants from plant tissue is also routine.

(F) and (G) The amount of direction provided by the present inventors is high and the claimed method is exemplified.

(H) The quantity of experimentation needed to make or use the invention is limited to selecting an appropriate marker gene that produces an auxin or auxin precursor and transforming it into a plant cell, selecting plant tissue having the phenotype conferred by the auxin or auxin precursor, and obtaining a transgenic plant from the selected tissue.

Based on the above analysis of the *In re Wands* factors and in view of the decision in *Capon*, the Applicants submit that the Examiner's concern that the selectable marker polynculeotides in Claim 6 be limited to specifically identified DNA sequences is misplaced. Genes which produce auxins or auxin analogs are well-known in the art, see *Woodward et al., id.* Similarly, while the specification describes selection media containing indoleacetamide or naphthalene acetamide, one with skill in the art would be able to easily select other auxin or auxin analogue precursors, since auxins and auxin precursors are also well-known in the art.

Budar et al., Prinsen et al., Sitbon et al., and Depicker et al. were cited as teaching that particular combinations of genes, such as *iaaH* and *iaaM* may interfere with plant physiology or result in abnormal growth or development.

Initially, the presence of inoperative embodiments within the scope of a claim does not necessarily render a claim non-enabled. The standard is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art, *Atlas Powder Co. v E.I. du Pont de Nemours & Co.*, 224 USPQ 409, 414 (Fed. Cir. 1984); MPEP 2164.08(b). For the reasons discussed above, the Applicants respectfully submit that no undue experimentation would be required to identify inoperative embodiments, if any, falling within the scope of the claims.

Moreover, Budar and Prinsen are not concerned with regenerating transgenic plants, but with experimentally determining expression of the *iaaH* or IAM synthetase genes in plants. Thus, these research groups would not have sought to select conditions for obtaining the transgenic plants of the present invention. Sitbon indicates that one with skill in the art could select an appropriate promoter for achieving desired morphological characteristics attributed to auxins (page 1062, col. 2, first full paragraph). Depicker was cited as indicating that positive selection in an auxin analogue precursor (NAM) containing medium is ineffective, possibly due to cross-feeding of tobacco cells lacking the auxin analogue synthesis gene (*iaaH*). However, they indicate that negative selection is effective. Since Claim 6 does not preclude negative selection, this document does not show that the claimed invention is not enabled. Moreover, based on the present disclosure and what is known in the art, one with skill in the art would have been able to avoid potential cross-feeding without undue experimentation.

Spena et al., Schmulling et al., and Estruch et al. were cited as teaching the unpredictability of using non-exemplified auxin synthesis genes as selectable markers. The issue is not whether some experimentation would be required to determine the suitability of a particular gene as a selectable marker, but whether undue experimentation would. Here, the Applicants submit that based on the present disclosure and on what is known in the art, one with skill in the art would be able to select the appropriate auxin synthesis genes for use as selectable markers in the claimed method without undue experimentation. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

Prior Art

The Applicants thank the Examiner for indicating that the claims are free of the prior art.

Claim 25

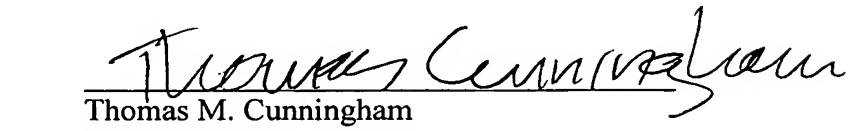
Claim 25 was rejected only on grounds of indefiniteness. In view of the amendment above, this claim should now be in condition for allowance.

CONCLUSION

In view of the above amendments and remarks, the Applicants respectfully submit that this application is now in condition for allowance. Early notification to that effect is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Norman F. Oblon



Thomas M. Cunningham
Registration No. 45,394

Customer Number
22850

Tel: (703) 413-3000
Fax: (703) 413 -2220
(OSMMN 06/04)
TMC/rac